OCT 2 5 2005 **510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052060.

Submitter Information

Address: Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

Contact person: Diana L. Wolaniuk, (610) 240-3917

Summary preparation date: October 25, 2005

Name of Device

Trade/Proprietary Name: ARCHITECT® CA 19-9™$_{XR}$ Assay

Common/Usual Name: CA 19-9 Assay

Classification Name: System, Test, Carbohydrate Antigen (CA19-9), For Monitoring And Management Of Pancreatic Cancer

Predicate Device

Fujirebio Diagnostics, Inc. CA 19-9 RIA

Device Description

The ARCHITECT CA 19-9$_{XR}$ assay is a two-step immunoassay for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®.

In the first step, sample and 1116-NS-19-9 coated paramagnetic microparticles are combined. 1116-NS-19-9 reactive determinants present in the sample bind to the 1116-NS-19-9 coated microparticles. After washing, 1116-NS-19-9 acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of 1116-NS-19-9 reactive determinants in the sample and the RLUs detected by the ARCHITECT *i* System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

Intended Use

Reagent Kit
The ARCHITECT CA 19-9$_{XR}$ assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma on the ARCHITECT *i* System. The ARCHITECT CA 19-9$_{XR}$ assay is to be used as an aid in the management of pancreatic cancer patients in conjunction with other clinical methods.

Patients known to be genotypically negative for the Lewis blood group antigen will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotypically positive for the Lewis antigen may produce varying levels of CA 19-9 based on gene dosage effect.

Calibrator Kit
The ARCHITECT CA 19-9$_{XR}$ Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma. Refer to the ARCHITECT CA 19-9$_{XR}$ reagent package insert for additional information.

Control Kit
The ARCHITECT CA 19-9$_{XR}$ Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System (reagents, calibrators, and instrument), when used for the quantitative measurement of 1116-NS-19-9 reactive determinants in human serum or plasma. Refer to the ARCHITECT CA 19-9$_{XR}$ reagent package insert for additional information.

Statement of Substantial Equivalence

The ARCHITECT CA 19-9$_{XR}$ assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma on the ARCHITECT *i* System. The ARCHITECT CA 19-9$_{XR}$ assay is to be used as an aid in the management of pancreatic cancer patients in conjunction with other clinical methods.

Patients known to be genotypically negative for the Lewis blood group antigen will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotypically positive for the Lewis antigen may produce varying levels of CA 19-9 based on gene dosage effect.

ARCHITECT CA 19-9 Assay kit is substantially equivalent to the Fujirebio Diagnostics, Inc. CA 19-9 RIA. Both of the devices are IVD products and are indicated for the quantitative determination of CA 19-9 assay values (1116-NS-19-9 reactive determinants) and used in conjunction with other clinical methods in the management of pancreatic cancer patients.

A comparison of the features of the ARCHITECT CA 19-9$_{XR}$ assay device and the Fujirebio Diagnostics, Inc. CA 19-9 RIA follows.

	Abbott Laboratories ARCHITECT CA 19-9™$_{XR}$ Assay (Proposed Device)	**Fujirebio Diagnostics, Inc. CA 19-9™ RIA (Predicate Device) K020566**
Device Type	*In vitro* diagnostic	*In vitro* diagnostic
Classification and Product Code	Class II, NIG	Class II, NIG
Principle of Operation	Chemiluminscent Microparticle Immunoassay (CMIA)	Radioimmunoassay (RIA)
Product Usage	Clinical and Hospitals laboratories	Clinical and Hospitals laboratories
Intended Use	The ARCHITECT® CA 19-9™$_{XR}$ assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma on the ARCHITECT *i* System. The ARCHITECT CA 19-9$_{XR}$ assay is to be used as an aid in the management of pancreatic cancer patients in conjunction with other clinical methods. Patients known to be genotypically negative for the Lewis blood group antigen will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotypically positive for the Lewis antigen may produce varying levels of CA 19-9 based on gene dosage effect.	The Fujirebio Diagnostics CA 19-9™ RIA, an *in vitro* diagnostic test for the quantitative measurement of the CA 19-9 tumor associated antigen, in human serum or plasma, is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful to aid in: *Monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum or plasma CA 19-9 above the cutoff, at the time of diagnosis.* CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.
Type of Specimen	Human serum or plasma (Sodium, Lithium or EDTA)	Human Serum or Plasma (Citrate, Heparin, ACD-A or EDTA)
Specimen Collection Method	Routine Phlebotomy Techniques	Routine Phlebotomy Techniques
Capture Antibody	1116-NS-19-9 mouse monoclonal	1116-NS-19-9 mouse monoclonal
Conjugate Antibody	1116-NS-19-9 (F(ab')2) mouse monoclonal	1116-NS-19-9 mouse monoclonal
Standards	6 levels (0 – 1200 U/mL)	6 levels (0 - 240 U/mL)
Controls	3 levels (Low = 40 U/mL, Medium = 150 U/mL, High = 750 U/mL)	2 levels (Low = 40-50 U/mL, High = 80-90 U/mL)
Interpretation of Results	Calibrator Curve	Standard Curve

Summary of Performance characteristics

Reproducibility:

Precision was determined as described in the National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-A2. Six samples were tested consisting of two panels of pooled serum (panels 1 and 2), one panel of serum to which 1116-NS-19-9 reactive determinants were added (panel 3), and the ARCHITECT CA 19-9$_{XR}$ Controls, using two lots of reagents, in replicates of two, at two separate times per day, for 20 nonconsecutive days on two instruments. Each reagent lot used a single calibration curve throughout the study. The total precision was determined by calculating the standard deviation (SD) and percent coefficient of variation (%CV) values for each sample.

The total precision %CV of the ARCHITECT CA 19-9$_{XR}$ assay was determined to be less than or equal to 10%.

Comparison Study

A total of 259 serum specimens were tested using the ARCHITECT CA 19-9$_{XR}$ assay and the Fujirebio Diagnostics, Inc. CA 19-9 RIA. Passing-Bablok linear regression analysis was performed on all specimens (2.0 – 9115.7 U/mL for the ARCHITECT CA 19-9$_{XR}$ assay and 1.17 – 10,782 U/mL for the Fujirebio Diagnostics, Inc. CA 19-9 RIA).

Passing-Bablok linear regression analysis comparing the ARCHITECT CA 19-9$_{XR}$ assay to the Fujirebio Diagnostics, Inc. CA 19-9 RIA yielded a correlation coefficient of 0.96, a slope of 1.2 (99% confidence interval of 1.08, 1.37), and Y-axis intercept of –5.1 U/mL (99% confidence interval of –7.4, -3.4).

Reference Ranges:

Apparently Healthy Population:
The distribution of CA 19-9$_{XR}$ assay values determined in 360 serum specimens from apparently healthy individuals is shown in the table below:

Distribution of ARCHITECT CA 19-9$_{XR}$ Values						
		Percent (%)				
	Number of Subjects	0 - 37.0 U/mL	37.1 - 100 U/mL	100.1 - 500 U/mL	500.1 - 1200 U/mL	> 1200 U/mL
Apparently Healthy Subjects	360	94.4%	5.6%	0.0%	0.0%	0.0%

In this study, 94.4% of the specimens from apparently healthy subjects (n=360) had values of 37 U/mL or less.

Patient Groups:

The distribution of CA 19-9 assay values determined in 978 individual serum samples from patients with malignant and non malignant diseases is shown in the table below:

Distribution of ARCHITECT CA 19-9$_{XR}$ Values						
		Percent (%)				
	Number of Subjects	0 - 37.0 U/mL	37.1 - 100 U/mL	100.1 - 500 U/mL	500.1 - 1200 U/mL	> 1200 U/mL
Nonmalignant Disease						
Rectal Polyps	33	97.0%	3.0%	0.0%	0.0%	0.0%
Pancreatitis	3	100.0%	0.0%	0.0%	0.0%	0.0%
Gallbladder	21	95.2%	0.0%	0.0%	0.0%	4.8%
Diabetes	38	94.7%	5.3%	0.0%	0.0%	0.0%
Pulmonary	40	100.0%	0.0%	0.0%	0.0%	0.0%
Cirrhosis	153	92.8%	4.6%	0.7%	0.7%	1.3%
Hepatitis	68	92.6%	7.4%	0.0%	0.0%	0.0%
Renal	34	91.2%	8.8%	0.0%	0.0%	0.0%
Other Gastrointestinal	51	96.1%	3.9%	0.0%	0.0%	0.0%
Malignant Disease						
Colorectal	169	81.1%	7.7%	5.3%	1.2%	4.7%
Pancreatic	66	43.9%	6.1%	12.1%	10.6%	27.3%
Gastric	69	66.7%	11.6%	10.1%	2.9%	8.7%
Hepatocellular	30	63.3%	16.7%	3.3%	10.0%	6.7%
Pulmonary	70	84.3%	5.7%	4.3%	1.4%	4.3%
Mammary	102	86.3%	10.8%	2.0%	1.0%	0.0%
Ovarian	31	87.1%	6.5%	3.2%	3.2%	0.0%

Pancreatic Cancer Serial Specimens

This analysis is based on 74 patients. There were a total of 261 evaluable observations. The average number of observations per patient is 3.5.

The average age of the subjects at time of diagnosis was 61.8 years (Exact 95% CI: 59.5 years to 64.1 years) with a range of 41 to 85 years. Fifty-five percent (55% or 41/74) of the 74 patients were men and the remaining forty-five percent (45% or 33/74) were women. Staging was available from the chart for 73 of the 74 patients. The majority of the patients were stage III and IV (41.9% and 40.5% respectively) while 4.1% and 6.8% were stage I and II respectively.

Association between Change in Marker Value and Change in Disease State

A 2x2 table was constructed to show the association between a positive change in a patient's CA 19-9 value and progression of the disease from one observation to the next. A positive change in CA 19-9 is defined as an increase in the value that is at least 2.5 times greater than the total %CV of the test. For the test assay this value is 14.0%. The following Table (entitled "Distribution of W by V") presents the results for the 187 observation pairs in this study.

Three estimates of Concordance are given for the following Table.

Total Concordance: $C = (16+98) / 187 = 114/187 = 61.0\%$

Positive Concordance: $C_+ = 16/33 = 48.5\%$

Negative Concordance: $C_- = 98/154 = 63.6\%$

Distribution of W by V

Change in CA 19-9 (V)	Change in Disease State (W)		Total
	Progression	No Progression	
≥ 14.0%	16	56	72
< 14.0%	17	98	115
Total	33	154	187

Per Patient Analysis

The table below (entitled " Per Patient Distribution) demonstrates this distribution for the 74 patients in this study.

Per-Patient Distribution

Change in CA 19-9	Change in Disease State		Total
	Progression	No Progression	
≥ 14.0%	15	16	31
< 14.0%	7	36	43
Total	22	52	74

Estimates of per-patient concordances can be obtained. Confidence intervals for these estimates can be determined using the binomial distribution. The following table (entitled" Estimate of Per-Patient Positive, Negative and Total Concordance with 95% confidence Intervals) demonstrates the estimates and 95% confidence intervals about each estimate.

Estimates of Per-Patient Positive, Negative and Total Concordance with 95% Confidence Intervals

Statistic	Estimate	Lower Bound	Upper Bound
C	68.92%	57.10%	79.17%
C_+	68.18%	45.13%	86.14%
C_-	69.23%	54.90%	81.28%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Fujirebio Diagnostics, Inc.
c/o Ms. Diana L. Wolaniuk
Clinical and Regulatroy Affairs Specialist
201 Great Valley Pkwy,
Malvern, PA 19355-1307

OCT 2 5 2005

Re: k052000
Trade/Device Name: ARCHITECT® CA 19-9™$_{XR}$ Assay, ARCHITECT® CA 19-9™$_{XR}$ Calibrator Kit and ARCHITECT® CA 19-9™$_{XR}$ Control Kit
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: NIG, JIT, JJX
Dated: July 21, 2005
Received: July 27, 2005

Dear Ms. Wolaniuk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052000

Device Name: ARCHITECT® CA 19-9™ $_{XR}$

Indications For Use:

ARCHITECT CA 19-9$_{XR}$ Reagent Kit
The ARCHITECT CA 19-9$_{XR}$ assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma on the ARCHITECT *i* System. The ARCHITECT CA 19-9$_{XR}$ assay is to be used as an aid in the management of pancreatic cancer patients in conjunction with other clinical methods. Patients known to be genotypically negative for the Lewis blood group antigen will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotypically positive for the Lewis antigen may produce varying levels of CA 19-9 based on gene dosage effect.

ARCHITECT CA 19-9$_{XR}$ Calibrator Kit
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ARCHITECT CA 19-9$_{XR}$ Control Kit
The ARCHITECT CA 19-9$_{XR}$ Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System (reagents, calibrators, and instrument), when used for the quantitative measurement of 1116-NS-19-9 reactive determinants in human serum or plasma. Refer to the ARCHITECT CA 19-9$_{XR}$ reagent package insert for additional information.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052000